



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.         | CONFIRMATION NO.       |
|--|-------------|----------------------|-----------------------------|------------------------|
| 10/573,036   | 03/22/2006  | Osamu Cynshi         | CYNshi 7                    | 4404                   |
| 1444 7590 01/11/2008<br>BROWDY AND NEIMARK, P.L.L.C.<br>624 NINTH STREET, NW<br>SUITE 300<br>WASHINGTON, DC 20001-5303 |             |                      | EXAMINER<br>BARTS, SAMUEL A |                        |
|  |             |                      | ART UNIT<br>1621            | PAPER NUMBER           |
|  |             |                      | MAIL DATE<br>01/11/2008     | DELIVERY MODE<br>PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/573,036 | <b>Applicant(s)</b><br>CYNSHI ET AL. |  |
|                              | <b>Examiner</b><br>Samuel A. Barts   | <b>Art Unit</b><br>1621              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 17-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating fatty liver or hepatic diseases, does not reasonably provide enablement for prevention of the same diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The pathways for causing fatty liver or hepatic diseases are too numerous and broadly diverse to reasonably expect a single compound to inhibit all of them. The prevention of such diseases is not enabling since said diseases have no recognized single cause. In fact, the aforementioned diseases are recognized as having many contributing factors, ranging from hereditary considerations, to lifestyle choices such as the weight and diet of a person. There are many more factors as to why people are inflicted with these diseases. Therefore, the prevention of said diseases by inhibiting one pathway is not enabled by the instant disclosure. Applicant should amend the claims to be commensurate in scope with treating fatty liver or hepatic diseases.

### ***Claim Objections***

2. Claims 18-31 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 18-31 are directed to a composition of matter. Independent claim 17 is directed a method of treatment. Composition of matter does not further limit a method of treatment claim. It is respectfully suggested that claims 18-31 be amended to recite the method of treating comprising the particular claimed composition.

Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 17-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamura et al (US 5,574,178) in view of Tsujii et al (US 5,043,354).

The instant claimed invention is directed to the use of compounds of formula 1 (shown in claim 1) to treat fatty liver or hepatic diseases. Tamura et al teach a genus which embraces the compounds used in the instant claim<sup>1</sup>. Tamura discloses that the compounds have antioxidant properties and are useful for treating diseases such as ischemia, arteriosclerosis and myocardial infarction.

---

<sup>1</sup> See columns 2-10.

Tamura fails to explicitly teach that the compounds could be useful for treating fatty liver or hepatic diseases.

Tsujii discloses benzofuran compound that are useful in the treatment of diseases caused by reactive oxygen species<sup>2</sup>. Tsujii lists ischemia, myocardial infarction as typical diseases that can be treated with the benzofuran compounds<sup>3</sup>. Tsujii also listed disorders of the liver as diseases that would be treatable using the benzofuran antioxidants. Thus Tsujii establishes that ischemia, myocardial infarction and disorders of the liver are treated by the same method.

It would have been obvious to one having ordinary skill in the art at the time that applicant's invention was made to have used the compounds of Tamura to treat disorders of the liver. Fatty liver and hepatic diseases are subgeneric to the phrase disorders of the liver. Thus a skilled artisan would have had a reasonable expectation of success in using the compounds in Tamura in the treatment of Fatty liver and hepatic diseases. One skilled in the art would have been motivated to use the compounds in Tamura to treat other diseases which are affected by the same mechanism.

***“When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical***

---

<sup>2</sup> This also means that the compounds are antioxidants. In this art, antioxidants are compounds that act to scavenge reactive oxygen species and organic radicals.

<sup>3</sup> See column 1 lines 35-46.

***grasp" (SUPREME COURT OF THE UNITED STATES, KSR INTERNATIONAL CO.  
v. TELEFLEX INC. et al, April 30, 2007; 550 U.S. 2007)***

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel A. Barts whose telephone number is 571-272-2870. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel A Barts/  
Primary Examiner  
Art Unit 1621

SB

Application/Control Number:  
10/573,036  
Art Unit: 1621

Page 6